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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/720,006	12/19/2000	Johann Karl	05-042	5872	
20306 7:	590 03/07/2006		EXAMINER		
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP			FOSTER, CH	FOSTER, CHRISTINE E	
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32ND FLOOR			ART UNIT	PAPER NUMBER	
CHICAGO, IL	CHICAGO, IL 60606				

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Applicant(s) Advisory Action 09/720.006 KARL ET AL. Before the Filing of an Appeal Brief Examiner Art Unit Christine Foster 1641 --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 22 February 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires _____months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). (a) They raise new issues that would require further consideration and/or search (see NOTE below): (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for

set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The Notice of Appeal was filed on 22 February 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of **AMENDMENTS** 3. 🔀 The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because appeal: and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) X will not be entered, or b) X will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: None. Claim(s) objected to: None. Claim(s) rejected: 44-52. Claim(s) withdrawn from consideration: 70-72. AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 13. ☐ Other: . Christoph L. Chin CHRISTOPHER L. CHIN

PRIMARY EXAMINER GROUP 1800-/64/

Continuation Sheet (PTO-303)

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Continuation of 3. NOTE:

Applicant's amendment filed 2/22/06 does not place the application in condition for allowance because the proposed amendments raise new issues that would require further consideration and search because the proposed amendments affect the scope of the claims. Independent claims 44, 49, and 51 have been amended to recite that the analyte comprises at least two "analyte-specific components" rather than at least two "epitopes", which represents a broadening in scope. Epitopes, which refer to different regions on an analyte, are deemed to represent a type of analyte-specific component. However, analyte-specific components could also include, for example, different polypeptide chains on a protein analyte.

In addition, newly added claims 73-74 recite that the analyte of claim 44 comprises two analyte-specific components that are two different analyte-specific antigens or antibodies. This represents a broadening in scope in that examined claim 44 was drawn to a method for the detection of "an analyte", i.e., a single analyte. The new claims, as well as amended claims 44, 49, and 51, now encompass that "an analyte" can refer to multiple analytes rather than a single analyte comprising two epitopes.

The proposed amendments also raise the issue of new matter because claim 49 now recites that an analyte-specific component bound to the first test area is not simultaneously bound to the second test area. Applicant indicated that support for this amendment could be found in Examples 2 and 3 of the specification, to which the Examiner disagrees. No support could be found for the limitation of an analyte-specific component bound to the first test area that is "not simultaneously bound" to the second test area.